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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,546	12/05/2003	Charles C. Raney	007404-000541	1896

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111 MONUMENT CIRCLE, SUITE 3700
INDIANAPOLIS, IN 46204-5137

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	**PAPER NUMBER**
3736	

NOTIFICATION DATE	DELIVERY MODE
10/24/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/729,546	RANEY ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-42 and 48-63* is/are pending in the application.

4a) Of the above claim(s) *35,36,42,48 and 57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,34,37-41,48-56 and 58-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/10/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 07/10/2007, amended claim(s) 33 and 40, canceled claim(s) 1-32 and 43-47, withdrawn claim(s) 35, 36, 42, 48, and 57, and new claim(s) 48-63 is/are acknowledged. The current rejections of the claim(s) 1-10, 14-18, and 21-23 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claims 37, 50-52, and 59-61 are objected to because of the following informalities: the positive recitations of "the sealing member has a hydrophobic

surface", "the top surface is hydrophobic", "the bottom surface is hydrophobic", and "the sealing member is hydrophobic" are ambiguous and may render the claims indefinite because as claimed it is unclear how or what structure is responsible for the claimed hydrophobicity. The Examiner notes Applicant may have intended to positively recite "the sealing member has a surface comprised of a hydrophobic material", "the top surface is comprised of a hydrophobic", "the bottom surface is comprised of a hydrophobic", "the sealing member is comprised of a hydrophobic", or the like. Appropriate correction is required.

5. Claim 55 is objected to because of the following informalities: the positive recitation of "the body" in line 1 appears to lack antecedent basis and may render claim indefinite. The Examiner notes Applicant may have intended to positively recite "the test strip". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 49 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 49 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the claimed limitation of a test strip including "an opening that opens" is ambiguous. It is unclear how an opening can open and/or what structure is responsible for the opening.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 33, 34, 37-41, 49-56, and 58-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishikawa et al. (US 6,315,738 B1, hereinafter Nishikawa).

11. For claims 33 and 40, Nishikawa discloses a sampling system, comprising:

- a test strip (32) configured for loading into a lancing device to analyze body fluid from an incision created by the lancing device (column 2 lines 57-63 and Abstract), wherein the test strip has a strip shape (as best seen in Figure 3), the test strip including
    - a test area (32) configured to analyze the body fluid (column 1 lines 5-14),
    - a sampling passageway (33) with an inlet opening (33a) that is remotely located from the test area (as best seen in Figures 4 and 12-23), the sampling passageway being sized and configured to draw the body fluid via capillary action (column 2 lines 26-31, column 4 lines 4-10, and column 10 lines 20-25), the sampling passageway extending from the inlet opening to the test area (as best seen in Figures 4 and 12-23) for transporting the body fluid from

the incision to the test area via capillary action (column 2 lines 26-31, column 4 lines 4-10, and column 10 lines 20-25),

- a bottom surface (the bottom of test strip support 38) that faces the skin (200) when the test strip is received in the lancing device (as best seen in Figures 21-23),
- a recessed surface (3a) extending between the inlet opening and the bottom surface to inhibit contact of the body fluid on the skin with the bottom surface of the test strip (as best seen in Figures 4 and 12-23), and
- a sealing member (34a, 34b, 34c, 34d) projecting outwardly from the bottom surface of the test strip proximal the inlet opening (as best seen in Figures 4 and 12-23) and positioned to seal with the skin when the test strip is pressed against the skin to retain the body fluid at the inlet opening (column 12 lines 6-39); and

- wherein the test strip with the sealing member is configured to be unloaded from the lancing device as a single disposable unit (column 2 lines 57-63 and Abstract).

12. For claims 34 and 41, Nishikawa discloses a sampling system, wherein: the test strip includes an end edge (the end edge of test strip support 38) and the inlet opening is defined in the end edge (as best seen in Figures 4 and 12-23).

13. For claim 37, Nishikawa discloses a sampling system, wherein the sealing member has a surface comprised of a hydrophobic material (column 11 lines 33-36) (the known hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

14. For claim 38, Nishikawa discloses a sampling system, wherein the sealing member is capable of being deformed upon pressing against the skin.

15. For claim 39, Nishikawa discloses a sampling system, wherein the test strip has a recessed surface (3a) extending between the inlet opening and the bottom surface (as best seen in Figures 4 and 12-23).

16. For claims 49 and 58, Nishikawa discloses a sampling system, wherein: the test strip includes a top surface positioned opposite the bottom surface (as best seen in Figures 4 and 12-23) and the test area includes an opening at the top surface of the test strip to permit reflectance of light for optical analysis (93) (as best seen in Figures 21-23).

17. For claims 50 and 59, Nishikawa discloses a sampling system, wherein: the test strip includes a top surface (the top of test strip support 38) positioned opposite the bottom surface (as best seen in Figures 4 and 12-23) and at least a portion of the top surface is comprised of a hydrophobic material to resist flow of the body fluid along the top surface (the known hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

18. For claims 51 and 60, Nishikawa discloses a sampling system, wherein at least a portion of the bottom surface (the bottom of test strip support 38) is comprised of a hydrophobic material (the known hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

19. For claims 52 and 61, Nishikawa discloses a sampling system, wherein the sealing member is comprised of a hydrophobic material (column 11 lines 33-36) (the

known hydrophobic polymers, including polypropylene, polyethylene, and polystyrene, positively recited in column 8 line 66 – column 9 line 7).

20. For claims 53 and 62, Nishikawa discloses a sampling system, wherein the recessed surface extends at an obtuse angle from the bottom surface to the inlet opening (as best seen in Figure 20).

21. For claims 54 and 63, Nishikawa discloses a sampling system, wherein the obtuse angle is from about 100 degrees to about 150 degrees (as best seen in Figure 20).

22. For claim 55, Nishikawa discloses a sampling system, wherein: the test strip has an end edge (the end edge of test strip support 38) and the inlet opening communicates with the end edge at a location spaced from the bottom surface (as best seen in Figures 4 and 12-23).

23. For claim 56, Nishikawa discloses a sampling system, wherein the test strip further includes first and second side edges (the side edges of test strip support 38) extending from the end edge, the sealing member extending from the first side edge to the second side edge (column 12 lines 6-39).

Response to Arguments

24. Applicant's arguments with respect to claims 33, 34, 37-41, 49-56, and 58-63 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)

272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

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